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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,420	11/26/2003	Stanley Beames Brown	0001530USQ/3049	2642
23117	7590	10/27/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			ROYDS, LESLIE A	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/723,420	Applicant(s) BROWN ET AL.	
	Examiner Leslie A. Royds	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-53 and 65-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 44-53 and 65-97 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 44-53 and 65-97 are presented for examination.

Applicant's response filed September 1, 2005 to the requirement for restriction dated July 1, 2005 has been received and entered into the application. Applicant's election of Group III, claims 44-64 and 70-78 has been noted. In response to the requirement, Applicant cancelled claims 54-64 and newly added claims 87-97 in lieu thereof and withdrew claims 65-69 from consideration.

Upon further consideration of the original claims and those claims newly added in Applicant's response filed September 1, 2005, the restriction requirement of July 1, 2005 has been **VACATED** due to the fact that claims 44-53 and 65-97 are drawn to several independent and patentably distinct inventions and compounds.

The following requirement set forth herein applies to the pending claim set 44-53 and 65-97 and supercedes the previous requirement of July 1, 2005.

Requirement for Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 53, 65-69, 80-83, 85-88 and 92, drawn to a compound of formula (I) or compositions comprising a compound of formula I and a diluent, excipient, polymer or attached surface or a compound formed by the reaction of a compound of formula (I) and a chlorotriazine derivative, classified in class 514, subclass 224.8.

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- II. Claims 44-52, 70-76 and 94, drawn to methods of treatment that require removal, deactivation or killing of unwanted tissues or cells or methods of treating precancerous conditions or cancer comprising the administration of a compound of formula (I), classified in class 514, subclass 224.8.
- III. Claims 70-76 and 94, drawn to methods of treating ophthalmologic diseases comprising the administration of a compound of formula (I), classified in class 514, subclass 224.8.
- IV. Claims 70-76 and 94, drawn to methods of treating vascular problems, arteriosclerosis or restenosis comprising the administration of a compound of formula (I), classified in class 514, subclass 224.8.
- V. Claims 70-76 and 94, drawn to methods of treating autoimmune diseases comprising the administration of a compound of formula I, classified in class 514, subclass 224.8.
- VI. Claims 70-76 and 94, drawn to methods of treating skin diseases comprising the administration of a compound of formula (I), classified in class 514, subclass 224.8.
- VII. Claims 77-79, 84, 89-91, 93 and 95, drawn to methods of treating microbial infections, burn wounds, dental bacterial disease, sterilization of a surface or fluid or antibiotic resistant bacteria comprising the administration or application of a compound of formula (I), classified in class 514, subclass 224.8.

VIII. Claims 96-97, drawn to methods of photochemical internalization, photodetection and photodiagnosis comprising the application of a compound of formula (I), classified in class 424, subclass 9.6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and Inventions II-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compound of formula (I) and the compositions containing a compound of formula (I) (identified as Group I) may also be used in a variety of materially different uses, such as (1) a dye, (2) treatment of cancer or precancerous conditions, (3) treatment of ophthalmologic diseases, (4) treatment of vascular problems, arteriosclerosis or restenosis, (5) treatment of autoimmune diseases, (6) treatment of skin diseases, (7) treatment of microbial diseases or infections, or (8) photochemical internalization, photodetection or photodiagnosis, each which require distinctly different process steps in different populations of subjects and with distinctly different outcomes, thus, supporting the fact that the inventions are independent and distinct.

Inventions II through VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of each of groups II-VIII each have a separate and distinct outcome from the expected outcome of any one or more of the other inventions. For example, the expected result

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of a method of treating arteriosclerosis is distinctly different than a method of treating cancer, since the desired outcome of a method of treating arteriosclerosis is the amelioration of artery blockage and enhancing normal cardiovascular function, while the desired outcome of a method of treating cancer is to arrest inappropriate overgrowth of cells and to thwart metastatic spread of cancerous cells. Furthermore, each of the methods would be practiced in distinctly different populations of patients. While there may be incidental overlap in the groups of patients experiencing, for example, arteriosclerosis, and those experiencing, for example, cancer, the therapeutic objectives, endpoints, steps and dosages required to treat such dissimilar conditions are vastly different and do not reasonably suggest the treatment of the other.

The distinct nature of groups II-VIII is further supported by the fact that each disease has a different and distinct etiology and pathophysiological manifestations, and that each is differently treated. Such is sufficient to indicate that each of the methods of treating the presently claimed disease states is differently searched in the patent and non-patent literature and that a search for one disease will not necessarily result in a comprehensive search of any one or more of the other diseases listed. As a result, an undue burden would be placed on the Examiner to search each of Applicant's claimed methods. Notwithstanding that Applicant may have established an underlying commonality for the claimed diseases, it remains that each of the diseases are recognized in the art as being clinically and pathophysiologicaly distinct from one another and, thus, each of the above-identified groups is fully capable of supporting separate patents.

Consideration of the plurality of inventions that Applicant has claimed would significantly compromise and preclude a quality examination on the merits. Furthermore,

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execution of a search encompassing the entirety of Applicant's compounds and multiple therapeutic objectives would not only constitute an undue burden on the Examiner, but *consideration of the findings* of such a search in accordance with the requirements of the law under 35 U.S.C. §§101, 102, 103 and 112 would be unduly onerous.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Should Applicant elect any one of the inventions of Groups I-IV, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of compound of formula (I) for prosecution on the merits to which the claims shall be restricted.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, a listing of all claims readable thereon, and a structural drawing of the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP

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§821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the Examiner withdraws the restriction requirement before the patent issues. See MPEP §804.01.

A telephone call was made to Mary J. Wilson at the office of Nixon and Vanderhye, P.C. on Friday, October 21, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

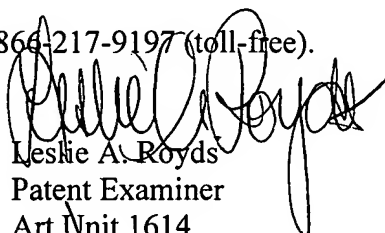
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie A. Royds
Patent Examiner
Art Unit 1614

October 21, 2005



WAYNE JONES
PRIMARY EXAMINER